

Cost-Effectiveness of Thoracic Patient-Controlled Epidural Analgesia Using Bupivacaine with Fentanyl vs Bupivacaine with Morphine after Thoracotomy and Upper Abdominal Surgery

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Objectives: To compare the effectiveness and cost of thoracic patient-controlled epidural analgesia (TPCEA) using bupivacaine with fentanyl (BF) vs bupivacaine with morphine (BM) solution.

Material and Method: In a blinded, randomized controlled trial, 90 adult patients who were scheduled for thoracotomy or upper abdominal surgery were enrolled. All patients were anesthetized by a combined general/epidural technique. Intraoperative and postoperative analgesia was provided by TPCEA using bupivacaine 0.0625% with either fentanyl (group BF) or morphine (group BM) solution. The occurrence and severity of side effects, visual analogue scale (VAS) for pain at rest and during movement, patients' satisfaction score as well as charged cost of pain and side effect management were recorded for 48 hrs.

Results: Demographic data of both groups were not significantly different. No statistical differences were noted with respect to efficacy of pain relief between the 2 groups. Only 28.5% of the patients in group BM required supplemental systemic analgesia within 24 hours after epidural catheter removal compared with 51.4% in the group BF. Patients' satisfaction and the severity of epidural analgesia related side effects, using itching and nausea/vomiting score, of both groups were not significantly different except the median nausea/vomiting scores of group BM at 18 and 24 hours were statistically higher than those of group BF ($P = 0.047$ and 0.02 , at 18 and 24 hour respectively) but not clinically different. The mean charged cost of medication used in group BM (470.64 ± 160.54 baht) was lower than that in group BF (814.15 ± 217.51 baht).

Conclusion: TPCEA using BF and BM solution resulted in similar pain relief and side effect profiles but with higher charged cost of medication in group BF. Morphine appears to be a more cost-effective choice than fentanyl for TPCEA after thoracotomy or upper abdominal surgery.

Keywords: Cost-effectiveness, Thoracic epidural analgesia, Thoracotomy, Abdominal surgery

J Med Assoc Thai 2005; 88(7): 921-7

Full text. e-Journal: <http://www.medassocthai.org/journal>

Thoracic epidural analgesia provides an excellent pain control after upper abdominal and thoracic surgery and has been shown to reduce morbidity and mortality of patients by improving pulmonary function and blunting surgical stress response⁽¹⁾. It has become an analgesic technique of choice for these operations in developed countries.

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Several analgesics have been successfully used to provide analgesia via this route⁽²⁾. Because of their synergistic effects, low concentration local anesthetics combined with narcotic are most commonly chosen⁽³⁾. Choice of narcotic, lipophilic vs hydrophilic opioid, has remained debatable. Fentanyl, widely considered as a surrogate of lipophilic opioids, offers less trouble some side effects which include pruritus, nausea, vomiting and more worrisome, delayed respiratory depression⁽⁴⁾. Morphine, a surrogate of hydrophilic

opioids, provides a significantly longer duration of analgesia and wider area coverage of pain control which can be explained by its better spreading in cerebrospinal fluid⁽⁵⁾. Some anesthesiologists routinely choose morphine for thoracic epidural analgesia because of the higher cost of fentanyl, but others would prefer to use fentanyl due to a higher incidence of side effects of morphine. In developing and poor countries, the cost of medication which is readily overlooked in wealthier countries needs to be carefully considered. Morphine itself is much cheaper than fentanyl and this benefit is more significant if analgesic duration is included into consideration. But, cost arising from management of side effects which are more common with the use of morphine may negate the benefits from its lower price. Thus, the present study is aimed to compare the effectiveness, side effects and cost of thoracic patient-controlled epidural analgesia (TPCEA) using bupivacaine with fentanyl (BF) vs bupivacaine with morphine (BM) solution.

Material and Method

After hospital investigational review board approval, 90 adult patients, ASA physical status 1-3 and aged between 18-80 years old, who were scheduled for thoracotomy or upper abdominal surgery at Siriraj Hospital were enrolled. Exclusion criteria included a history of allergic reaction to bupivacaine, fentanyl or morphine, history or laboratory results suggesting any evidence of coagulopathy, obstructive sleep apnea, central neurological disease, chronic pain, infection of skin or subcutaneous tissue at the epidural insertion site, ASA physical status > 3, emergent surgery, non-functioning epidural catheters, unable to report pain score or use PCA (patient-controlled analgesia) machine from any reasons. Patients were randomly assigned to receive TPCEA with either bupivacaine with fentanyl (group BF) or bupivacaine with morphine (group BM) solution in the postoperative period.

In the preoperative period, the details of the present study process including potential side effects of thoracic patient-controlled epidural analgesia were explained to all the patients before written informed consent was obtained. All patients included into the present study were taught how to use the patient-controlled analgesia machine and how to give visual analogue pain scale (0-100) for pain, itching and nausea/ vomiting level grading.

During the intraoperative period, all patients received intravenous balanced salt solution before thoracic epidural catheter placement. After the patient

was placed on standard monitors (non-invasive blood pressure, ECG, pulse oximeter), epidural catheters were placed at the thoracic level of 6 to 8 for thoracotomy and of 8-10 for upper abdominal surgery and inserted about 4 cm into the epidural space using the standard technique. After negative aspiration, test dose using 3 ml of 2% lidocaine with epinephrine 5 mcg/ml was injected through the catheter. No motor blockade or increased heart rate within 3 minutes after injection excluded unintentional subarachnoid or intravascular catheter placement. All the patients received general anesthesia which was maintained by oxygen/ nitrous oxide or air/ inhalational agent/ muscle relaxant. No opioids were given either intravenously during the preoperative and intraoperative period except one dose of fentanyl ≤ 2 mcg/kg during the induction period. Intraoperative analgesia was provided by thoracic epidural analgesia using intermittent injection of 0.25% bupivacaine. Approximately 30 minutes to 1 hour before completion of performing surgery, epidural loading dose contained in the 10 ml syringe labeled "study drug for epidural use" (either morphine 2 mg for group BM or fentanyl 50 mcg group BF diluted in preservative-free normal saline 10 ml) was given through an epidural catheter.

In the postoperative period, once extubated and being sufficiently awake to follow the instructions, the patients were reminded about the use of PCA machine and visual analogue scale in the recovery room. Thoracic patient-controlled epidural analgesia management was as follows. Epidural solution (contained in 160 ml bag) was 0.0625% bupivacaine with fentanyl 3 mcg/ml in group BF and 0.0625% bupivacaine with morphine 30 mcg/ml in group BM. The PCA machine settings in both groups were 3 ml/hr for basal rate, 3 ml for PCEA bolus, 15 min for lockout interval and 60 ml for 4-hour limit. At 48 hr. after extubation, the epidural catheter was removed and conventional pain management according to the surgical team was commenced. During the study period, lasting for 48 hr after extubation, all the patients were monitored according to the protocol as follows: blood pressure and heart rate every 4 hr, respiratory rate every 1 hr for 12 hr then every 2 hr for 12 hr and then every 4 hr for 24 hr.

During the study period, side effect management was standardized according to the following protocol. Patients who had nausea or vomiting and requested treatment initially received metoclopramide 10 mg prn every 6hr intravenously. If the symptom was not improved within 1 hr after treatment, ondansetron

setron 4 mg was given intravenously and could be repeated at the same dose in half an hour if needed protracted nausea or vomiting. Patients who had pruritus and requested treatment received diphenhydramine 25 mg prn every 6 hr intravenously. If the symptom had not improved within 1 hr after treatment, nalbuphine 2.5 mg would be administered intravenously. If patients experienced respiratory rate less than 10 breath/min, they would be initially treated with intervention necessary to assure adequate airway patency, oxygenation and ventilation. Epidural infusion would be discontinued. Naloxone 1 mcg/kg would be administered intravenously followed with 1mcg/kg/hr continuous infusion which would be tapered off as indicated clinically.

Data collection included demographic data, visual analogue pain scale (0-100, 0 = no pain, 100 = most severe pain imaginable) at rest and on movement as well as nausea/vomiting and pruritus scale (0-100, 0 = no symptom, 100 = worst symptom) as reported by patients were recorded at 6, 18, 24, 30, 42 and 48 hr after extubation by the observers who were blind to the narcotic used. Satisfaction score (0-100, 0 = least satisfaction, 100 = most satisfaction) was recorded 2 times at 24 and 48 after completion of surgery by the same observer. Cost and charges of all medications related to pain control of each patient were calculated and recorded at the end of the study. Cost of nurse workload was not included.

Statistical analysis

The sample size was calculated by using the program SAM; a sample size calculator and the incidence of pruritus, 5% with fentanyl and 30% with morphine⁽⁴⁾, was utilized for calculation (control proportion = 0.05, treated proportion = 0.3, confidence

level = 0.95, power = 0.8). The sample size was equal to 40 patients/group.

Descriptive statistics was used to describe the data. To analyze the differences between the group, Chi-square and Fisher Exact test were used for categorical data. Unpaired T-test and Mann Whitney U test were used for continuous data. P value of less than 0.05 was declared as statistically significant. Cost included charged cost of all medications used that related to pain control. Pain score, patients' satisfaction, and side effects represented effectiveness.

Results

Ninety patients were randomly enrolled into the present study. Eleven patients were excluded, 4 non-functioning epidural catheters and 7 accidental catheter removals. Of the rest 79 patients, 40 and 39 patients were in group BF and BM respectively.

No differences were noted between the two groups with respect to age, weight, height, types of surgery, anesthetic time, surgical time and amount of 0.25% bupivacaine given during surgery (Table 1).

Median of pain VAS scores at rest and at movement, itching as well as nausea/vomiting VAS scores were similar between the groups without statistical significance except nausea/vomiting scores at 18 and 42 hours of group BM was statistically higher than those of group BF, P value = 0.047 and 0.02 respectively (Table 2).

Only 28.5% (10/35) of patients in group BM required supplemental systemic analgesia within 24 hours after epidural catheter removal compared with 51.4% (18/35) in group BF.

The number of patients requiring treatment for pruritus and nausea/vomiting at different frequency were also similar in both groups (Table 3, 4).

Table 1. Demographic data (mean \pm SD with range in parenthesis)

Demographic data	Group BF (n = 40)	Group BM (n = 39)	p value
Age (yr)	50.30 \pm 12.06	47.12 \pm 11.11	0.22
Height (cm)	159.28 \pm 9.43	160.54 \pm 7.31	0.54
Weight (kg)	57.11 \pm 8.83	57.22 \pm 9.74	0.95
Type of surgery			
Thoracotomy	19 (47.5%)	18 (46.2%)	
Upper abdominal surgery	21 (52.5%)	21 (53.8%)	
History of PONV	0 (0%)	2 (5.1%)	0.14
Anesthetic time (min)	151.92 \pm 60.73	166.41 \pm 79.23	0.36
Surgical time (min)	123.94 \pm 60.44	130.43 \pm 67.75	0.65
Bupivacaine given during surgery	10.30 \pm 5.06	12.05 \pm 4.83	0.12

Table 2. VAS of pain at rest, pain on movement, pruritus, nausea/vomiting and satisfaction (median with interquartile range in parenthesis)

Variable	Group BF	Group BM	p value
Resting pain score at			
6 hr	20 (0.75-47.5)	10 (0-30)	0.86
18 hr	20 (3.5-30)	0 (0-20)	0.23
24 hr	20 (5-30)	10 (0-20)	0.35
30 hr	10 (0-23.75)	10 (0-20)	0.77
42 hr	5 (0-20)	5 (0-20)	0.55
48 hr	0 (0-20)	0 (0-10)	0.68
Moving pain score at			
6 hr	50 (20-70)	40 (10-50)	0.10
18 hr	40 (26.25-50)	30 (10-50)	0.29
24 hr	40 (20-60)	30 (10-50)	0.20
30 hr	30 (20-47.5)	40 (10-50)	0.98
42 hr	30 (20-40)	30 (10-50)	0.98
48 hr	20 (16.25-47.5)	20 (10-40)	0.63
Itching score at			
6 hr	0 (0-20)	5 (0-20)	0.51
18 hr	7.5 (0-30)	10 (0-30)	0.68
24 hr	10 (0-30)	10 (2-30)	0.39
30 hr	15 (0-30)	20 (5-30)	0.29
42 hr	0 (0-20)	10 (0-30)	0.06
48 hr	2.5 (0-20)	10 (0-20)	0.44
Nausea and vomiting score at			
6 hr	0 (0-10)	0 (0-10)	0.94
18 hr	0 (0-0)	0 (0-10)	0.047*
24 hr	0 (0-8.75)	0 (0-10)	0.55
30 hr	0 (0-0)	0 (0-5)	0.27
42 hr	0 (0-0)	0 (0-2)	0.02*
48 hr	0 (0-0)	0 (0-0)	0.27
Satisfaction score at			
24 hr	100 (80-100)	100 (80-100)	0.99
48 hr	100 (90-100)	100 (80-100)	0.41

* p value < 0.05

Table 3. Number of patients required treatment for pruritus

Number of treatment	Number of patients	
	Fentanyl (n = 40)	Morphine (n = 39)
0	24	24
1	9	8
2	2	3
3	3	2
4	1	0
5	1	2

Table 4. Number of patients required treatment for nausea/vomiting

Number of treatment	Number of patients	
	Fentanyl (n = 40)	Morphine (n = 39)
0	31	29
1	7	4
2	0	5
3	1	0
4	1	1

Mean charged cost of epidural solution and medication used in group BM (470.64 ± 160.54 baht)

was lower than that in group BF (814.15 ± 217.51 baht) (Table 5).

Table 5. Details of charged cost of medication for thoracic epidural analgesia (mean \pm SD with range in parenthesis)

Cost	BF (baht)	BM (baht)
Epidural infusion	765.00 \pm 210.43	420.10 \pm 137.57
Itching therapy	46.90 \pm 63.49	48.10 \pm 72.23
Nausea/vomiting therapy	2.25 \pm 6.40	2.43 \pm 5.11
Total	814.15 \pm 217.51	470.64 \pm 160.54

Discussion

It was shown in recent meta-analysis that thoracic epidural analgesia using local anesthetics with opioids provided excellent postoperative pain relief in patients after thoracic and upper abdominal surgery. In that report, morphine and fentanyl were the predominant choices of epidural opioid⁽⁶⁾. Several studies have shown that continuous epidural analgesia with BF and BM solution resulted in similar quality of analgesia⁽⁷⁻⁹⁾. This is consistent with the present result that median VAS pain at rest and on movement were not statistically or clinically different between the 2 groups. However, the mean VAS of pain at rest and on movement reported in meta-analysis were 11.3 and 24.7 for thoracic surgical site as well of thoracic epidural analgesia as 9.0 and 27.4 for abdominal surgery which appears to be better than the results especially incident pain. This may be simply explained by the technique of patient controlled analgesia utilized in the present study. To prevent significant pain on movement, additional bolus of epidural solution must be self administered by patients 5-10 minutes before ambulation. Even though this technique had been instructed and encouraged to all of the enrolled patients, the practice in reality may be rather sporadic than consistent as the culture of Thais, and may also be in other Asian populations, toward self administered medication technique and toward post-operative pain is different from patients from developed countries. Fear of using sophisticated equipment to give medication to oneself is not unexpected in Thai patients. Moreover, acceptance of postoperative pain as a requisite after operation is common. The mean epidural solution used in group BF = 4.68 cc/hr and group BM 4.09 cc/hr which is only 1-1.5 cc/hr more than the basal rate of 3 cc/hr of PCA machine setting, supported the above postulation. Study to compare efficacy of epidural analgesia by continuous infusion and patient-controlled technique in an Asian population may be warranted to clarify this issue.

Despite controversy surrounding its spinal analgesic effect, fentanyl is still widely used for

epidural infusion because of its lower incidence of side effects than morphine. Epidural BF is associated with less emesis and an increased ability to tolerate oral fluids and shorter hospital stay after major abdominal gynecological cancer⁽¹⁰⁾. The side effects of epidural opioids are related to their rostral spread in the cerebrospinal fluid (CSF) to supraspinal structures. Following epidural injection, the concentration of morphine in CSF is far in excess of that in plasma and are present even up to 24 hr later⁽¹¹⁾. Fentanyl, a much more lipophilic opioid, has more rapid access to CSF and then it is quickly uptaken by spinal vein which resulted in increased its plasma concentration and less free drug to migrate rostrally to the brain. Regarding pruritus, nausea and respiratory depression during continuous epidural infusion using opioid alone without local anesthetics, morphine was shown to result in a significantly higher incidence of side effects than fentanyl⁽¹²⁾. In the present study, the median VAS of nausea/vomiting and pruritus of both groups was very low and clearly not clinically different. The incidence of patients who requested treatment for nausea/vomiting at least 1 time in the first 48 hr after surgery were 22.5% and 25.8% in group BF and BM respectively. This incidence was higher than previously reported of 6% and 9% when using bupivacaine-fentanyl and bupivacaine-morphine epidural solution⁽⁸⁾. The mean dose of narcotic used was lower in the present study; fentanyl 14.04 mcg/hr in group BF and morphine 122.7 mcg/hr in group BM than that in the study by Saito et al which was 20 mcg/hr of fentanyl and 200 mcg/hr of morphine. Thus, a higher dose of narcotic is not an explanation. The authors postulated that the aim of the present study was to look at the incidence of side effects and its cost, therefore special attention was paid to this aspect while in the study by Saito, side effect was an indirect result. This may also be the reason that the incidence of pruritus in the present study was slightly higher than previously reported⁽⁸⁾. The authors believe that the incidence in the present study may be more accurate and clinical relevant to the real situation.

The surprising result of the present study was that the incidence of nausea/vomiting and pruritus was almost exactly the same between both groups in terms of incidence and severity. The explanation for these results is unclear. The proposed mechanism may be that rostral spreading of fentanyl to the brain which is believed to be the acting site of epidural opioid related side effect, is more readily with thoracic epidural analgesia. However, in Saito's study⁽⁸⁾, with a similar level thoracic epidural site of T5-9 and similar dose of narcotic, the reported incidence of nausea/vomiting and pruritus was significantly less in the fentanyl group than morphine. The mechanism of the difference between the result of the present study and Saito's study is unclear. The authors proposed the possibility of the effect of genetic difference which required further study.

The present results show that TPCEA with BF and BM solution provided similar postoperative analgesia at rest and during movement as well as equally low degree of pruritus and nausea/vomiting. Because the incidence of common side effects of both groups was shown to be indifferent, the cost of medication for the management of side effects was subsequently indifferent. The discrepancy of the charged cost of medication related to pain management is, therefore, from the difference of the cost of narcotic in epidural solution (the mean amount of solution used per hour were minimally different) which is lower in group BM.

Conclusion

TPCEA using BF and BM solution resulted in similar pain relief and side effect profiles but with higher charged cost of medication in group BF. Morphine appears to be a more cost-effective choice than fentanyl for TPCEA after thoracotomy or upper abdominal surgery.

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การศึกษาประสิทธิผลของการให้ยาระงับปวดทางช่องเหนือไขสันหลังระดับทรวงอกเปรียบเทียบระหว่างมอร์ฟีน (morphine) กับเฟ็นทานิล (fentanyl) ในผู้ป่วยที่มารับการผ่าตัดทรวงอกหรือช่องท้องส่วนบน

ทรงยศ วลัยถาษา, พชรี มาบุญญานนท์, ธนาภรณ์ นภาโชติ, บุศรา ศิริวันสาณฑ์, สุวรรณีย์ สุรเศรษฐ์

วัตถุประสงค์: เพื่อศึกษาประสิทธิผลและราคาของการระงับปวดด้วยวิธีการให้ยาเข้าช่องเหนือเยื่อหุ้มไขสันหลังระดับทรวงอกแบบควบคุมด้วยตัวผู้ป่วยเองด้วย bupivacaine ผสมกับ fentanyl เปรียบเทียบกับ bupivacaine ผสมกับ morphine

วัสดุและวิธีการ: เป็นการศึกษาแบบสุ่มตัวอย่างในผู้ป่วย 90 คน ที่มารับการผ่าตัดที่ช่องอกหรือช่องท้องส่วนบน ผู้ป่วยทุกคนได้รับการดมยาสลบร่วมกับการใส่สายเข้าช่องเหนือเยื่อหุ้มไขสันหลังเพื่อให้ยาระงับปวด โดยกลุ่ม BF ได้รับ bupivacaine ร้อยละ 0.0625 ร่วมกับ fentanyl และกลุ่ม BM ได้รับ bupivacaine ร้อยละ 0.0625 ร่วมกับ morphine บันทึกอุบัติการณ์และความรุนแรงของผลข้างเคียง คะแนนความปวดขณะพักและเคลื่อนไหว คะแนนความพึงพอใจของผู้ป่วย และราคารวมของยาที่ใช้ในการระงับปวดและการรักษาผลข้างเคียงทั้งหมด เป็นเวลา 48 ชั่วโมง

ผลการศึกษา: ลักษณะของกลุ่มประชากรที่เข้ารับการศึกษาคณะคุณภาพการระงับปวดของทั้ง 2 กลุ่มไม่แตกต่างกัน ผู้ป่วยร้อยละ 28.5 ของกลุ่ม BM ต้องการยาระงับปวดเข้ากลามหรือหลอดเลือดดำภายใน 24 ชั่วโมง หลังเอาสายช่องเหนือเยื่อหุ้มไขสันหลังออก เปรียบเทียบกับกลุ่ม BF ต้องการยาถึงร้อยละ 51.4 ต้องการยา ความพึงพอใจของผู้ป่วย คะแนนความคันและคะแนนความคลื่นไส้ อาเจียน ไม่แตกต่างกัน ยกเว้น ค่ามัธยฐานของคะแนนของอาการคลื่นไส้อาเจียนที่ 18 และ 42 ชั่วโมง ของกลุ่ม BF น้อยกว่า กลุ่ม BM อย่างมีนัยสำคัญทางสถิติ แต่ไม่ต่างกันเมื่อพิจารณาทางคลินิก ราคาของยาที่ใช้ในการระงับปวดและการรักษาผลข้างเคียงของกลุ่ม BM และ BF เท่ากับ 470.64 ± 160.54 บาท และ 514.15 ± 217.51 บาท ตามลำดับ

สรุป: การระงับปวดหลังผ่าตัดเข้าช่องทรวงอกหรือช่องท้องส่วนบน ด้วยวิธีให้ยาเข้าช่องเหนือไขสันหลังแบบควบคุมด้วยตัวผู้ป่วยเองด้วย bupivacaine ผสมกับ morphine มีความคุ้มค่าในด้านประสิทธิผลและราคามากกว่าการใช้ bupivacaine ผสมกับ fentanyl
